

WHAT IS CLAIMED IS:

1. An electrochemical test device for determining the presence or concentration of an analyte in an aqueous fluid sample, said electrochemical test device comprising:

- 5
- (a) a non-conductive surface;
 - (b) a working electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said working electrode having an first electrode area, a first lead and a first contact pad;
 - 10 (c) a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said counter electrode having an second electrode area, a second lead and a second contact pad; and
 - (d) a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or
 - 15 concentration of the analyte in the fluid sample, said reagent overlaying at least of portion of the first electrode area of the working electrode.

2. The electrochemical test device of Claim 1 wherein said device further comprises a reference electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said reference electrode having a

20 third electrode area, a third lead, and a third contact pad, and wherein at least a portion of the third electrode area is overlaid with a reference material.

3. The electrochemical test device of Claim 2 wherein said reference

25 material is silver/silver chloride.

4. The electrochemical test device of Claim 1 wherein the non-conductive surface comprises a non-conductive coating affixed to one side of a flexible metallic material.

5. The electrochemical test device of Claim 1 wherein the non-

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conductive surface comprises a flexible polymeric sheet material or a non-conductive coating affixed to one side of a flexible polymeric sheet material.

1 6. The electrochemical test device of Claim 5 wherein the polymeric
5 sheet material is selected from the group consisting of polyesters, polycarbonates and polyimides.

5 7. The electrochemical test device of Claim 4 wherein the non-
conductive coating is an epoxy resin.
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8. The electrochemical test device of Claim 1 wherein the amorphous semiconductor material is amorphous silicon oxide.

9. The electrochemical test device of Claim 8 wherein the
15 amorphous silicon oxide is doped with an ion to increase conductivity.

10. The electrochemical test device of Claim 9 wherein the amorphous silicon oxide is doped with lithium.

20 11. The electrochemical device of Claim 1 where the amorphous semiconductor material is gold.

sub a3 12. The electrochemical device of Claim 1 where the amorphous
semiconductor material is silver.
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13. The electrochemical test device of Claim 1 wherein the reagent comprises an enzyme and a redox mediator.

14. The electrochemical test device of Claim 13 wherein the enzyme
30 is glucose oxidase.

15. The electrochemical test device of Claim 14 wherein the redox mediator is potassium ferricyanide.

16. The electrochemical test device of Claim 1 wherein the
5 electrochemical test device further comprises a blood separating membrane.

17. A method for determining the presence or concentration of an analyte in an aqueous fluid sample, said method comprising:

- 10 (a) providing an electrochemical test device comprising: (i) a non-conductive surface; (ii) a working electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said working electrode having an first electrode area, a first lead and a first contact pad; (iii) a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said counter electrode having a second electrode
15 area, a second lead, and a second contact pad; and (iv) a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or concentration of the analyte in the fluid sample, said reagent overlaying at least of portion of the first electrode area of the working electrode;
- 20 (b) inserting the electrochemical test device into a meter device;
- (c) applying a sample of an aqueous fluid to the first electrode area of the working electrode;
- (d) reading the meter device to determine the presence or
25 concentration of the analyte in the fluid sample.

18. The method of Claim 17 wherein the electrochemical test device further comprises a reference electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said reference electrode having a third electrode area, a third lead, and a third contact pad, and wherein at least
30 portion of the third electrode area is overlaid with a reference material.

19. The method of Claim 18 wherein the reference material is silver/silver chloride.

20. The method of Claim 17 wherein the non-conductive surface
5 comprises a non-conductive coating affixed to one side of a flexible metallic
material.

21. The method of Claim 20 wherein the non-conductive surface comprises a flexible polymeric sheet material or a non-conductive coating affixed to one side of a flexible polymeric sheet material.

22. The method of Claim 21 wherein the polymeric sheet material is selected from the group consisting of polyesters, polycarbonates and polyimides.

15 23. The method of Claim 20 wherein the non-conductive surface
coating is an epoxy resin.

24. The method of Claim 17 wherein the amorphous semiconductor material is amorphous silicon oxide.

25. The method of Claim 24 wherein the amorphous silicon oxide is doped with an ion to increase conductivity.

26. The method of Claim 25 wherein the amorphous silicon oxide is
25 doped with lithium.

27. The method of Claim 17 where the amorphous semiconductor material is gold.

30 28. The method of Claim 17 where the amorphous semiconductor
material is silver.

29. The method of Claim 17 wherein the reagent comprises an enzyme and a redox mediator.

30. The method of Claim 29 wherein the enzyme is glucose oxidase.

31. The method of Claim 29 wherein the redox mediator is potassium ferricyanide.

32. The method of Claim 17 wherein the electrochemical test device further comprises a blood separating membrane.

33. A process for preparing an electrochemical test device suitable for determining the presence or concentration of an analyte in an aqueous fluid sample, said process comprising the steps of:

(a) providing a non-conductive surface;
(b) depositing an amorphous semiconductor material on said surface to form a conductive layer;
(c) chemically machining the conductive layer to form a working electrode comprising a first electrode having a first electrode area, a first lead and a first contact pad, and to form a counter electrode comprising a second electrode having a second electrode area, a second lead and a second contact pad; and

(d) applying a reagent to at least a portion of the first electrode area of the working electrode, said reagent being capable of reacting with an analyte in an aqueous fluid sample to produce a measurable change in potential which can be correlated to the concentration of the analyte in the fluid sample.

34. The process of Claim 33 wherein step (c) further comprises forming a reference electrode comprising a third electrode having a third electrode area, a third lead and a third contact pad.

35. The process of Claim 33 wherein step (a) above comprises the steps of:

(f) providing a flexible substrate;

(g) applying a non-conductive coating to the substrate to form a non-conductive surface.

36. The process of Claim 35 wherein the flexible substrate is a metallic sheet material or a polymeric sheet material.

37. The process of Claim 36 wherein the polymeric sheet material is selected from the group consisting of polyesters, polycarbonates and polyimides.

38. The process of Claim 35 wherein the non-conductive surface coating is an epoxy resin.

39. The process of Claim 33 wherein the amorphous semiconductor material is amorphous silicon oxide.

40. The process of Claim 39 wherein the amorphous silicon oxide is doped with an ion to increase conductivity.

41. The process of Claim 40 wherein the amorphous silicon oxide is doped with lithium.

42. The process of Claim 33 where the amorphous semiconductor material is gold.

43. The process of Claim 33 where the amorphous semiconductor material is silver.

44. The process of Claim 33 wherein the reagent comprises an

enzyme and a redox mediator.

45. The process of Claim 44 wherein the enzyme is glucose oxidase.

5 46. The process of Claim 45 wherein the redox mediator is potassium ferricyanide.

47. The process of Claim 33 wherein the electrochemical test device further comprises a blood separating membrane.

10 48. The process of Claim 33 wherein step (c) further comprises the steps of:

(h) applying a photoresist to the conductive layer to form a first photoresist layer;

15 (i) positioning a first developer mask on the first photoresist layer;

(j) exposing the unmasked first photoresist layer to ultraviolet light to form a first patterned photoresist area;

(k) removing the first developer mask;

20 (l) removing the first photoresist layer not exposed to ultraviolet light with a developer to form a first exposed conductive layer;

(m) contacting the first exposed conductive layer with a chemical etchant to remove the first exposed conductive layer;

25 (n) removing the first patterned photoresist area with a solvent to form a second exposed conductive layer, said second exposed conductive area comprising (i) a working electrode comprising a first electrode having a first electrode area, a first lead and a first contact pad, (ii) a counter electrode comprising a second electrode having a second electrode area, a second lead and a second contact pad, and optionally (iii) a reference electrode comprising a third electrode having a third electrode area, a third lead and a third contact pad.

30 49. The process of Claim 48 wherein step (c) above further comprises

the steps of:

- (o) applying a photoresist to the second exposed conductive layer to form a second photoresist layer;
- (p) positioning a second developer mask on the second photoresist so
5 that the second photoresist layer covering the third electrode area is masked;
- (q) exposing the unmasked second photoresist layer to ultraviolet light to form a second patterned photoresist layer;
- (r) removing the second developer mask;
- (s) removing the second photoresist layer not exposed to ultraviolet
10 light with a developer to expose the third electrode area;
- (t) applying a reference material the third electrode area;
- (u) removing the second patterned photoresist layer with a solvent.

50. The process of Claim 44 wherein the reference material is
15 silver/silver chloride.

51. A process of Claim 33 wherein said process is continuous.

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C4

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